OMB No. 0925-0637

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**PROTECTION OF HUMAN SUBJECTS ASSURANCE/CERTIFICATION/DECLARATION**

☐ ORIGINAL ☐ FOLLOWUP ☐ EXEMPTION (previously undesignated)

☐ GRANT ☐ CONTRACT ☐ FELLOW ☐ OTHER

☐ New ☐ Competing continuation ☐ Noncompeting continuation ☐ Supplemental

APPLICATION IDENTIFICATION NO. *(if known)*

*POLICY: A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless an Institutional Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act as implemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46—as revised). The applicant institution must submit certification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) which applies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the proposed activity should submit certification of IRB review and approval with each application. (In exceptional cases, certification may be accepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have an assurance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request from HHS for certification.*

1. TITLE OF APPLICATION OR ACTIVITY

Risk Factors for Acute Episodes of Wheezing in Infants and Children

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

Peter W. Heymann, M.D.

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION *(see reverse side)*

4. HHS ASSURANCE STATUS

☒ This institution has an approved assurance of compliance on file with HHS which covers this activity.

M1343 Assurance identification number 01XB IRB identification number

☐ No assurance of compliance which applies to this activity has been established with HHS but the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request.

5. CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION

☒ This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This certification fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device *(see reverse side of this form)*.

_____ Date of IRB review and approval. *(If approval is pending, write "pending". Followup certification is required.)*
*(month/day/year)*

☐ Full Board Review ☒ Expedited Review

for continuation of previously approved protocol

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated and that appropriate further certification *(Form HHS 596)* will be submitted.

☐ Human subjects are involved but this activity qualifies for exemption under 46.101(b) in accordance with paragraph _____ *(insert paragraph number of exemption in 46.101(b), 1 through 5)*, but the institution did not designate that exemption on the application.

**6. Each official signing below certifies that the information provided on this form is correct and that each institution assumes responsibility for assuring required future reviews, approvals, and submissions of certification.**

| APPLICANT INSTITUTION | COOPERATING INSTITUTION |
|---|---|
| NAME, ADDRESS, AND TELEPHONE NO.<br>University of Virginia Health Sciences Ctr<br>Charlottesville VA 22908<br>(804) 924-2109 | NAME, ADDRESS, AND TELEPHONE NO. |
| NAME AND TITLE OF OFFICIAL *(print or type)*<br>John A. Owen, Jr., M.D., Chair<br>Human Investigation Committee | NAME AND TITLE OF OFFICIAL *(print or type)* |
| SIGNATURE OF OFFICIAL LISTED ABOVE *(and date)*<br>John A. Owen, Jr. 6/24/93 | SIGNATURE OF OFFICIAL LISTED ABOVE *(and date)* |

HHS 596 (Rev. 1/82) *(If additional space is needed, please use reverse side under "Notes.")*

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Source: https://www.industrydocuments.ucsf.edu/docs/sjnm0000